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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,823	HAJJAJ ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-26* is/are pending in the application.

4a) Of the above claim(s) *11-13,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 14-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30 and 1031/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CLAIMS STATUS

1. Claims 1-9 are cancelled

2. Claims 11-13 and 25-26 are withdrawn.

3. Claims 10-26 are pending.

Restriction/Election

4. Applicants' election of Group I encompassing Claims 10 and 14-24 filed 06 December 2004 in response to Office Action dated 26 November 2004 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL

Citing the Office Action referred *supra*, applicants remark that the method claims, currently withdrawn (i.e., Claims 12-13 and 25-26) should be allowed upon finding that composition claims currently being prosecuted are patentable. This is because, applicants remark, that those method claims depend on, and would have all the patentable features of the claims currently being prosecuted.

Applicants' remarks regarding rejoining claims 12-13 and 25-26 to Claims currently constituting invention of Group I (i.e., Claims 10 and 14-24) have been carefully and fully considered. If the currently prosecuted claims constituting the invention in Group I (i.e., Claims 10 and 14-24) are found allowable, Examiner has already informed the applicants in the Office action cited above that the withdrawn Claims 12-13 and 25-26 will be given due consideration for patentability in accordance with the provisions of *In re Ochiae.*

Accordingly, Claims 11-13 and 25-26 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP §821.03. Examiner suggests that to expedite prosecution, the non-elected claims (i.e., Claims 11-13 and 25-26) cited *supra* be canceled in response to this Office action.

5. Claims 10 and 14-24 are examined on merits.

Information Disclosure Statement

6. Applicants' Information Disclosures (i.e., IDS) filed 30 July, and 31 October 2003 have been made of record and considered.

Priority

7. Applicants' claim for foreign priority under 35 U.S.C.§ 119(a-d) to PCT/EP02/00787 filed 24 January 2002, and to European Patent Office (EPO) 01102218.3 filed 31 January 2001is acknowledged. However, Applicants cannot rely upon the foreign priority papers to overcome this objection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Objection To Specification

8. 35 U.S.C. §112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms or description, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. §112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: e.g., Page 12, line 01, "A lipid extraction is carried out". Applicants should define what material is being extracted for lipid. Similarly, Page 12, Line 22 recites, "—less than 14 μg/ml". It is not clear from this sentence what reference is that number of 14 μg/ml is? At Page 16, the description under the heading "example 1" is very confusing. For example at Lines 4-5, the recitation, " 5 gms of dried fruit of *Pleurotus eryngii*" is unclear because *Pleurotus eryngii* does not bear a fruit as the term fruit is known in the pertinent art. The art-known term is "fruiting body". It is not clear what is being dissolved to get an aqueous extract of 100 mg. Is the extract 100 mg in weight? In Table 3, applicants present data on hypocholesterolaemic activity of ganoderol A, ganoderol B and ganoderic acid, however, applicants do not show/describe anywhere in the specification that these compounds are oxolanosteols or oxygenated natural compounds of lanosterol. The examiner suggests that the applicants carefully revise the specification including the abstract to make the specification consistent and clearly comprehendible. Applicants are warned to be careful to not add any new matter while revising the application for corrections to eliminate inexact or verbose terms.

Examiner has not checked the entire specification to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicants are warned to be careful to not add any new matter while revising the application for corrections to eliminate any verbose or incorrect terms/language.

OBJECTION TO ABSTRACT

9. The abstract of the disclosure in this application recites," with methods of use of the agent for preventing the synthesis of cholesterol in a person. These methods include the administration of the agent alone or in a food or beverage". However, within the four corners of the examples presented in the specification of the disclosure, no where is an example of feeding the composition of the claimed invention to a human being, or a food or beverage composition comprising the claimed materials, i.e., alleged oxylanosterol compounds (e.g., of ganoderol A, ganoderol B and ganoderic acid) that has been fed to a human being to lower the cholesterol synthesis in a human subject, or in a subject. Applicants have demonstrated inhibited cholesterol synthesis in cultured human hepatic cells (See page 11, Lines 17-27 for e.g.). Appropriate correction is required. Applicants are warned to be careful to not add any new matter while revising the abstract for corrections to eliminate any verbose or incorrect description.

Claim Rejections - 35 U.S.C. § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 22-24 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

From the record of the presently filed written disclosure, the specification enables only the preparation of a material comprising ganoderol A, ganoderol B and ganoderic acid from steeping dried fruiting bodies of *Ganoderma lucidum* and *Pleurotus citrinopileatus* (See e.g., Examples 1, 3, 8, 10-11, Page, Lines 17-27 and data presented in Table 3) and further the data presented in Table 1 on extracts obtained from different fungi. The description also demonstrates lowering of cholesterol synthesis in cultured human hepatic cells under in-vitro conditions because those cells are cultured. From the currently presented written specification and examples therein, as claimed in Claims 22-24, there is no showing that:

"an amount of extract from 1 to < 14μg /ml of the extract lowers cholesterol synthesis by 50% when in contact with human hepatic cells *in vivd*',

"an edible composition for inhibiting "cholesterol synthesis "in a person comprising a food or beverage".

Thus, in the absence of demonstrated evidence of record that said composition was administered to a human, whereupon said composition elicited cholesterol lowering or lowering of cholesterol synthesis in said human, the claimed invention is not considered enabled.

A person of skill would not be able to practice the invention because undue experimentation will be required to obtain claimed invention. The person of skill will not be able to practice the claimed invention due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Undue experimentation will be necessary because there is no recited guidance, i.e., to conduct human trials to administer claimed material to human beings in food or beverage

12. Claims 20 and 22-24 are rejected under 35 U.S.C. § 112, first paragraph, because the claimed composition does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure, the scope of the claimed invention recited in claims 20 and 22-24 is not supported by the specification on record because in said specification the working example demonstrates that the pH of the aqueous solution was adjusted to a pH of 3 (See specification, Page 16, Line 10). Claims 22-24 are not supported because applicants have only demonstrated inhibition of cholesterol synthesis in cultured human cells treated with the extracts obtained from different fungi according to the steps recited in the invention (See, examples 1-11 and data presented in Tables 1-3), but have neither demonstrated said cholesterol synthesis inhibition via administering said composition to a human being in a food or beverage nor by any other means of administration commonly known in the art. Thus, in the absence of demonstrated evidence of record that cholesterol synthesis was inhibited upon administering said preparations//compositions/agents to an individual, the specification is not commensurate in scope with those claims.

13. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

14. Claims 10 and 14-24 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- Claim 10 is rendered unclear, vague, and therefore, indefinite because of the phrase,

" hypocholesterolaemic agent". Is the agent a particular compound, a mixture of compounds merely an oxygenated lanosterol, a mixture of oxygenated lanosterols or a mixture comprising lanosterol and several compounds that are oxygenated lanosterols? If the claimed " hypocholesterolaemic agent" is comprised of several oxygenated lanosterols and those compounds have been identified, and the specification supports that identification and composition, the claimed invention would be better understood by claiming the exact composition of instantly claimed " hypocholesterolaemic agent". Examiner strongly recommends that applicants being cautious to not add/claim any new matter should claim the defined " hypocholesterolaemic agent" for better understanding of the claimed subject matter.

- Claim 10 is incomplete in the absence of a recovery step for the product produced. While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. The metes and bounds of the claimed steps are therefore not clearly established or delineated.

- The phrase, "rich in oxygenated" renders Claim 10 unclear, vague and therefore indefinite because said phrase does not establish the metes and bounds for the claimed subject matter. Appropriate clarification is required.

- Applicants have defined the recitation, "natural derivatives" in the specification. However, the recitation, "derivatives" in claim 10 renders that Claim unclear as well as confusing, and therefore indefinite because said recitation does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the recitation does not define the metes and bounds of the claimed subject matter. Appropriate correction is required.

- The recitation "obtainable" renders Claim 10 indefinite because this recitation in and by itself denotes a futuristic event. The metes and bounds of the claimed subject matter are not clearly defined. The examiner suggests that the applicants define the metes and bounds of the term "obtainable".

- As defined in the specification, the recitation, "edible fungus" encompasses any fungus that can be eaten as grown or supplemented to a food. Members of *Aspergillus, Penicillium* and some other non-basiomycetous fungi are routinely utilized in "oriental foods (e.g., koji, miso paste etc.) From the discussion in specification, it is not clear if the phrase; "edible fungi" encompasses those fungi and food preparations comprising them. If those fungi are encompassed in the term, "edible fungi", the recitation, "edible fungus" in the context of claim 10 renders that Claim

unclear as well as confusing, and therefore indefinite because said recitation does not clearly define whether those fungi are basidiomycetes or ascomycetes. Appropriate clarification is required.

- The phrase, "active" renders Claim 10 unclear, vague and therefore indefinite because said phrase does not establish the metes and bounds for the claimed subject matter. Appropriate clarification is required.

- Claims 10 and 17 are rendered vague and indefinite because of the term "extract". This term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by process since product-by-process claims are intended to define products that are otherwise difficult to define (and/or distinguish from the prior art). For example, from what part(s) of the fungus is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the necessary functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the steps(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991). Accordingly, without the recitation of all these critical limitations as set forth above, the cited claims do not adequately define the instant invention. Applicants have defined some of the conditions, solvents and other important, essential steps, however, the claimed subject matter, i.e., extract" will be better understood if all the conditions, steps, solvents and other pertinent information is incorporated within the body of said claims.

- The recitation "conditions sufficient" in Claim 10 renders that claim vague, unclear and indefinite. It is not clear how one can determine with clarity and accuracy when the condition is sufficient and a condition that is sufficient or appropriate in one case, may not be sufficient for another. Applicant is advised to define the metes and bounds for the recitation "condition sufficient".

All other claims depend directly from the rejected claim (e.g., Claim 103) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

16. Claims 10, 14-15 and 17-20 are rejected under 35 U.S.C. § 102(b) as anticipated by Nishitoba et al. (Agric. Biol. Chem., Volume 49, Pages 1793-1798, 1985).

Claims 10, 14-15, 17-20 and 23 recite a hypocholesterolaemic agent comprising oxygenated natural derivatives of lanosterol, said agent having been obtained via different steps, wherein fruiting body of "edible fungi" is extracted with solvents of variable polarities. One of the edible fungi being *Ganoderma lucidum.*

Nishitoba et al. teach a compound/agent obtained via extracting *Ganoderma lucidum* dried fruiting bodies, wherein extraction is conducted with solvents of varying polarities, the extract is performed with the fraction at a pH in range of 3-4, extraction performed with chloroform and finally obtained solid residue fractioned with silica gel chromatography (Page1796, Column 2, Line39 to Page 1797, Column 1, Line 2). Thus, Nishitoba et al inherently teach a hypocholesterolaemic fraction (i.e., ganodermic acid) because the prior art reference is obtaining a compound that is hypocholeserolaemic according to same product by process steps applying same components and reagents and methods as recited in the instantly claimed invention.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR §1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § *102*(f) or (g) prior art under 35 U.S.C.§ 103(a).

19. Claims 22-24 are rejected under 35 U.S.C. § 103(a) as obvious over Nishitoba et al. (Agric. Biol. Chem., Volume 49, Pages 1793-1798, 1985) in view of mushroom soup administered to a person.

Claims recite lowering of cholesterol synthesis in human hepatic cells *in vivo* when said cells are brought in contact with 1-14μg of a fungal extract, wherein fungal extract is of *Ganoderma lucidum* or *Pleurotus citrinipileatus* (i.e., mushroom). Claims further recite an edible composition comprising food or beverage to inhibit cholesterol, wherein said composition comprises said fungal extract.

Teachings from Nishitoba et al. as discussed *supra* teach preparation of a fungal extract, wherein said fungal extract is from *Ganoderma lucidum*. Nishitoba et al., however, do not teach inhibiting cholesterol lowering in human hepatic cells brought in contact with said extract *in vivo*. They also do not teach a food composition comprising said extract. However, a person eating mushroom soup is intrinsically eating a mushroom extract (i.e., *Pleurotus* sp. Extract) and said extract is ultimately getting in contact with hepatic cells *in vivo*, wherein it will have the same effect as instantly claimed and recited.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to combine the mushroom extract prepared according to Nishitoba et al. and incorporate it in art-known mushroom making process to obtain the invention instantly claimed, because Nishitoba et al. explicitly describe a composition comprising the oxylanosterol, wherein oxylanosterol is ganodermic acid and said composition is prepared according to the instantly claimed steps and ingredients. Upon incorporating into mushroom soup, said composition would have the instantly claimed effect.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine Nishitoba et al's teachings of preparing a fungal extract with art-well known conventional food composition preparation and administering said composition to lower cholesterol synthesis in human hepatic cells *in-vivo*. The prior art does not teach the exact same concentration/conditions as instantly claimed. However, the adjustment of particular conventional working conditions (e.g., the quantities of each one of components in a composition, temperature etc.) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

20. For reasons aforementioned, no Claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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RALPH GITOMER
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GROUP 1200

March 3, 2005